

**Rational Pharmaceutical Management Plus  
Technical Assistance to Support Program Implementation for the  
President's Emergency Plan for AIDS Relief, Kenya and the  
Antiretroviral Therapy Program in Mombasa, Kenya: Trip Report  
August 9 – 27, 2004**

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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## **Acronyms**

ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral [drugs]
CPGH	Coast Provincial General Hospital
FHI	Family Health International
GOK	Government of Kenya
HIV	human immunodeficiency virus
ICRH	International Centre for Reproductive Health
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
MEDS	Mission for Essential Drugs & Supplies (MEDS)
MOH	Ministry of Health [Kenya]
MSH	Management Sciences for Health
NASCOP	National AIDS and Sexually Transmitted Diseases Control Programme [Kenya]
OHA	[USAID] Office of HIV/AIDS
PEP	post exposure prophylaxis [for HIV]
PMO	Provincial Medical Officer [Coast Province]
RPM	Rational Pharmaceutical Management Plus [Program]
SO4	[USAID/Washington] fourth strategic objective
SOP	standard operating procedure
USAID	U.S. Agency for International Development



## **Background**

### **Antiretroviral Therapy Program in Mombasa, Kenya**

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program has received funding from the United States Agency for International Development (USAID) under USAID's fourth strategic objective (SO4) to collaborate with Family Health International (FHI)/Implementing AIDS Prevention and Care Project (IMPACT) and Population Council/Horizons to support the Government of Kenya (GOK) and local partners to introduce antiretroviral therapy (ART) into the existing health care system of four facilities in the Mombasa District of Kenya's Coast Province, as part of a comprehensive package of prevention, care and treatment. The Mombasa ART Program will provide valuable implementation and operations research on how to safely and effectively deliver antiretrovirals (ARVs) and how to build capacity to expand access to treatment. The dissemination of assessment and implementation results, tools, and lessons learned is an important component of this activity.

In September 2001, RPM Plus accompanied representatives from USAID/Office of HIV/AIDS (OHA) and USAID/Kenya to meetings with the Minister of Health, the Permanent Secretary for Health, the Minister of Public Health, the Director of Medical Services and the Chairman of the Pharmacy and Poisons Board of Kenya to discuss the Mombasa ART Program, drug registration, procurement and other drug management issues. RPM Plus also accompanied representatives from OHA, Kenya Mission, FHI/IMPACT, and Horizons on a site visit to Mombasa where the team met with the Provincial Medical Officer (PMO) for Mombasa, the Chief Administrator and Chief Pathologist at Coast Provincial General Hospital (CPGH), and local partners.

In April 2002, RPM Plus along with FHI/IMPACT and Horizons participated in a workshop in Mombasa with local partners, stakeholders and GOK Ministry of Health (MOH) to finalize the proposal and to draw up a timeline for the assessment.

In September 2002, RPM Plus conducted an assessment of the capacity of the pharmaceutical management system and laboratory services to support the introduction of ART in 4 sites in Mombasa, in addition to assessing current access to and use of ARVs in Mombasa city.

In November 2002, RPM Plus presented the results of a pharmaceutical management system and laboratory services assessment conducted from September 5 to 29, 2002 at a meeting of stakeholders. Invited participants included members of the Steering Committee and also other key stakeholders and partners, including representatives from the four sites.

In January 2003, RPM Plus met with the implementation team and key partners at each of the four sites to present and solicit feedback on the results of the pharmaceutical management system and laboratory services assessment. In addition, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at CPGH to select and prioritize options and recommendations to develop an implementation plan in preparation for the start up of the Mombasa ART Program.

Capacity building activities at CPGH began in January 2003 and an initial multidisciplinary

training was held at the end of March 2003. CPGH was the first of the four proposed implementing sites to begin delivering ART – ARVs were dispensed to the first patient on June 3, 2003. RPM Plus has been providing ongoing technical assistance to CPGH to support implementation of strategies to strengthen the pharmaceutical management system and laboratory services to support the start up and scale up the ART Program in addition to working with the other sites to prepare for the introduction of ART.

In November 2003, RPM Plus conducted a review of the Mombasa ART Program six months after the introduction of ART at CPGH in collaboration with FHI/IMPACT and Horizons. RPM Plus focused on the technical issues for the pharmaceutical management system and laboratory services, FHI/IMPACT on clinical services and overall implementation, and Horizons on operations research.

In October and November 2003, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at Port Reitz District Hospital and Bomu Medical Centre to select and prioritize options and recommendations to develop implementation plans in preparation for roll out of the ART Program. Capacity building began at the two sites in January 2004 and ARV delivery began at Bomu Medical Centre in June 2004 and at Port Reitz District Hospital in August 2004.

In June 2004, RPM Plus in collaboration with FHI and Horizons, held a meeting with CPGH staff to review and update clinical, pharmacy and laboratory implementation plans in light of the findings of the six-month review conducted in November 2003 and also to address evolving problems as the program rolls out.

### **The President's Emergency Plan for AIDS Relief, Kenya**

RPM Plus has received Track 1.5 funding from USAID's Kenya Mission under the President's Emergency Plan for AIDS Relief to:

- Strengthen pharmaceutical services in support of ART in selected sites Provincial General, District and Mission Hospitals
- Provide technical support to clinical teams implementing ART services
- Support national coordination of antiretroviral drug treatment
- Provide drugs and supplies for Emergency Plan-supported sites between April and September 2004
- Provide initial support to Mission for Essential Drugs & Supplies (MEDS) for infrastructure strengthening and procurement of ARVs and other essential commodities for ART

RPM Plus is applying and adapting the approaches, tools and lessons learned from the Mombasa ART Program to contribute to strengthening pharmaceutical services to support ART roll out in priority sites.



## **Purpose of Trip**

Ms. Helena Walkowiak traveled to Kenya from August 9 to 27, 2004 to work with Mrs Jedida Wachira, Senior Program Associate, MSH/RPM Plus, Mombasa to provide site-specific technical support for the roll out of the ART Program in Mombasa and also to work with GOK National AIDS and Sexually Transmitted Diseases Control Programme (NASCO) and local partners to conduct site visits to priority ART sites in Kenya to identify site level commodity management needs.

## **Scope of Work**

### **Scope of work for Ms. Helena Walkowiak, Senior Program Associate RPM Plus**

0. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.

### **Mombasa ART Program (August 9 to 14, 2004)**

0. At the request of the Scientific Committee, assist CPGH to develop a standard operating procedure for Post Exposure Prophylaxis (PEP).
0. Assist CPGH to revise Pharmacy and Laboratory Implementation Plans for the ART program based on the results of the review meeting of June 2, 2004.
0. Assist CPGH to analyze ART Adverse Drug Reaction (ADR) data collected to date.
0. Provide technical assistance to Bomu Medical Centre to review and address pharmaceutical and laboratory issues arising from ART start up.
0. Hand over manual ART quantification methodologies for testing at CPGH and Bomu Medical Centre.
0. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate.

### **The President's Emergency Plan for AIDS Relief, Kenya (August 15 to 27, 2004)**

0. Work with the regional RPM Plus office to develop a plan jointly with NASCO for priority site visits to identify site level commodity management needs.
0. Work with NASCO to conduct site visits to priority sites.
0. Plan for next steps to support NASCO ART commodity strengthening efforts.



## **Activities**

### **0. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested**

On August 27, 2004, Ms. Walkowiak met and debriefed Dr. John Wasonga and Dr Bedan Gichanga, USAID/Kenya on RPM Plus activities during the visit. Ms Walkowiak gave an update on capacity strengthening activities for both the pharmaceutical management systems and the laboratory services in support of ART roll out at the four sites in Mombasa and plans for next steps. Ms Walkowiak also debriefed Dr Wasonga and Dr Gichanga on the initial findings of the four site visits conducted by the NASCOP/RPM Plus team led by Ms Walkowiak.

### **Mombasa ART Program (August 9 to 14, 2004)**

### **0. At the request of the Scientific Committee, assist CPGH to develop a standard operating procedure for PEP**

At The Scientific Meeting held on August 4, RPM Plus was requested to assist CPGH to develop initially flowcharts and then a standard operating procedure (SOP) that describes the flow of clients and drugs to complement the clinical SOP. Ms Walkowiak met with the Dr Mandaliya, CPGH Pathologist and Chair of the Scientific Committee on August 12 and Dr Olwande, Pharmacist in Charge of the ART Program at CPGH on August 13 to map out the PEP procedures firstly for occupational exposure and secondly for rape to cover obtaining PEP ARVs for scenarios when the pharmacy is open and when it is closed. Next steps are for RPM Plus to draft flowcharts for review and comment by CPGH staff.

### **0. Assist CPGH to revise Pharmacy and Laboratory Implementation Plans for the ART program based on the results of the review meeting of June 2, 2004**

On June 2nd 2004, CPGH organized a meeting to review and update CPGH Implementation Plans for Clinical Services, Pharmacy and Laboratory. The meeting was supported by USAID through RPM Plus. The objectives of the meeting were:

- To carry out a structured review of the 2003 ART Implementation plans for CPGH to determine: what is completed, what is pending, emerging or remaining challenges, and new activities for incorporation
- To revise the plans based on the above findings and new CPGH roles to support ART scaling up within CPGH, roll-out to Bomu Medical Centre, Port Reitz District Hospital, and Magongo Municipal Clinic and for national ART scale up.

Ms Walkowiak and Mrs Wachira met with Dr Shikely, Chief Administrator at CPGH on August 11 to plan for implementation of the next steps to assist CPGH to a) incorporate issues raised at the meeting into the pharmacy and laboratory implementation plans and b) review each activity, assign a priority and determine who will carry out the activity, who will provide resources and a timeline for action. Dr Shikely requested that RPM Plus assist CPGH to prepare the draft updated pharmacy and laboratory implementation plans for CPGH review and action. Next steps are for RPM Plus to prepare draft updated pharmacy and laboratory implementation plans for CPGH review.

**0. Assist CPGH to analyze ART ADR data collected to date**

This activity was postponed as Dr Olwande, Pharmacist in charge of the ART Program at CPGH, did not have time to work on this activity due to other demands. It was agreed that the activity would be postponed until the computer was installed at CPGH so that Excel spreadsheets could be used to assist in the analysis – installation is currently scheduled for November 2004.

**0. Provide technical assistance to Bomu Medical Centre to review and address pharmaceutical and laboratory issues arising from ART start up**

Bomu Medical Centre dispensed ARVs to the first patient under the ART Program on June 2, 2004. Ms Walkowiak and Mrs Wachira held meetings with Mr Mehboob Abbas, Purchasing Officer on August 10, Dr Omesete, Medical Officer in Charge of the ART Program on August 10, 12 and 13, Ms Kudura Akida, Pharmacy Technician and Mr Musa Mwamzuka, Laboratory Technologist on August 12 to review start up issues for the ART Program at Bomu Medical Centre. Unfortunately, Ms Walkowiak was unable to meet with Mr Julius Kitunga, Pharmacy Staff in charge of the ART Program who had been called away for a week of site visits. The Program was reported to be working well, and the issues discussed included, ARV transport issues from CPGH to Bomu Medical Centre, correct use of the Expiry Date Monitoring Chart, funding of laboratory reagents and kits for the ART Program patients and operationalising the ADR monitoring and reporting system for the ART Program. Ms Walkowiak drafted a standard operating procedure for ADR monitoring and reporting – the forms and procedure are now on test. The review of SOPs for pharmacy following testing was postponed due to the absence of Mr Kitunga.

**0. Hand over manual ART quantification methodologies for testing at CPGH and Bomu Medical Centre**

This activity was postponed due to the absence of Mr Kitunga, Pharmacy Staff in charge of the ART Program at Bomu Medical Centre and the busy schedule of Dr Olwande, Pharmacist in charge of the ART Program at CPGH.

**0. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate**

***CPGH Eligibility Committee Meeting on August 12, 2004***

Ms. Walkowiak and Mrs Wachira attended the weekly meeting to review eligibility of new patients for the program. Representatives from Yale University attended the meeting and discussed potential collaboration with CPGH to provide services for intravenous drug users at CPGH.

***Meeting with Port Reitz District Hospital Pharmacy and Laboratory staff on August 13, 2004***

Ms Walkowiak met with Dr Ibrahim Abdulla, Pharmacist and Mr Mohammed Mwakuzimu, Laboratory Technologist-in-charge to discuss start up issues at Port Reitz District Hospital. The

pharmacy have a secure cupboard and air-conditioning in the ARV storage area and are ready to support start up of the ART Program. Some additional renovations are still needed but are not delaying start up. The laboratory is still waiting for equipment to arrive but have arrangements in place to send samples to CPGH Laboratory in the interim.

***Meeting with FHI/IMPACT to discuss ARV Procurement Issues on August 13, 2004***

Ms Walkowiak met with Dr Maurice Aluda, FHI/IMPACT and FHI consultant Mr Darsi Lotay to discuss procurement issues with a particular focus on streamlining the process for ordering supplies of ARVs, exchanging short dated stock, identifying new ARV products to be procured and forecasting of needs. RPM Plus assisted CPGH Pharmacy to quantify requirements for the seventh order to be placed using USAID funding since the start up of the program.

***Meeting with CPGH Pharmacy and Laboratory staff to develop debriefing presentations following their attendance at the XV International AIDS Conference in Bangkok for CPGH staff***

Ms Walkowiak assisted Dr Olwande and Mr Denje, CPGH Laboratory Supervisor to prepare presentations to debrief CPGH staff on their poster presentations and attendance at the XV International AIDS Conference in Bangkok, Thailand on July 14, 2004. The three posters were handed over to CPGH to display in their facility:

- *Scaling up access to ART in resource-limited settings: integrating ART programs into existing pharmaceutical management systems to support sustainable quality care in Mombasa, Kenya*
- *Strengthening good laboratory practices in resource-limited settings to support the introduction and scale up of ART: a case from Coast Provincial General Hospital, Mombasa, Kenya*
- *Access to HIV/AIDS-related Medicines: A Framework for Measurement*

**The President's Emergency Plan for AIDS Relief, Kenya (August 15 to 27, 2004)**

**0. Work with the regional RPM Plus office to develop a plan jointly with NASCOP for priority site visits to identify site-level commodity management needs**

On August 5, 2004, Dr Michael Thuo, Dr Joseph Mukoko and Mrs Jedida Wachira from the RPM Plus Regional Office met with Dr Cecilia Muiva and Dr Doreen Kagai from MOH/NASCOP to identify sites for the assessment, to determine teams and to plan for the logistics for the site visits. On August 15, Ms Walkowiak joined the RPM Plus team from the regional office in Nairobi to plan for and conduct site visits to identify site-level commodity management needs. RPM Plus assisted NASCOP to hold a 2 day meeting to review and finalise the assessment tool, define teams and roles of each member and finally to agree a common approach to collecting data, presenting initial findings to site staff for validation and prioritization of needs and reporting results. Logistics for the trip were also finalized. Ms Walkowiak was appointed team leader of one of the four groups.

**0. Work with NASCOP to conduct site visits to priority sites**

From August 17 to 27, Ms Walkowiak worked with the NASCOP/MOH team to conduct site visits to Kericho District Hospital, Kisii District Hospital, Kakamega Provincial Hospital and St Mary Mumias Mission Hospital. Team members included Dr Jao Majimbo, Chief Pharmacist with Kenya Ports Authority, Dr James Wariero, Pharmacist in Charge of the ART Program at Nyanza Provincial Hospital, Dr Susan Saddimbah, Pharmacist in Charge of the ART Program at Kenyatta National Hospital and Dr Amanda Ombeva from MOH/KEMSA.

The team worked with site staff to identify gaps and to prioritize needs for:

- Existence and availability of policies, guidelines and standards (including standard operating procedures) for ART
- Human resource capacity – staffing and training
- Infrastructure and equipment
- Selection, procurement (including quantification) and distribution systems for ARVs
- ARV prescribing, dispensing and use by the patient
- Management information system – including forms, registers and tools in use
- Monitoring and supervision
- Financing

Quantitative data was collected on

- Availability and stock outs of ARVs
- Prescription review to identify issues around prescribing
- Observation of dispensing practice
- Record keeping

Needs/gaps were prioritized according to the following categories:

- Gaps that needed to be addressed immediately to stop the program collapsing
- Gaps/needs needed to improve the program
- Needs for scaling up

The reports of the site visits were written up and handed over to the NASCOP/RPM Plus team by Ms Walkowiak on August 26, 2004.

## **0. Plan for next steps to support NASCOP ART commodity strengthening efforts**

A debriefing meeting was held on August 28, 2004 of all the teams and initial findings shared with NASCOP and local partners. Next steps are to finalise the report, prioritise needs and assign responsibilities to address gaps. RPM Plus will provide assistance to NASCOP as requested.

## **Collaborators and Partners**

### **USAID**

John Wasonga, USAID/Kenya  
Bedan Gichanga, USAID/Kenya

***FHI/IMPACT***

Darsi Lotay, FHI consultant  
Aluda Maurice, FHI/Mombasa  
Ruth Odindo, FHI/Mombasa

***Population Council/Horizons/International Centre for Reproductive Health (ICRH)***

Susan Kaai, Population Council/Nairobi  
Paul Munyao, ICRH/Mombasa

***Mombasa Site staff***

CPGH Management and Implementation Team  
Port Reitz District Hospital Management and Implementation Team  
Bomu Medical Centre Management and Implementation Team  
Magongo Municipal Clinic Implementation Team

***NASCOP***

Cecilia Muiva  
Doreen Kagai

***ART Implementing Site staff***

Kericho District Hospital  
Kisii District Hospital  
Kakamega Provincial Hospital  
St Mary Mumias Mission Hospital

***NASCOP/RPM Plus Site Visit Team Members***

Jao Majimbo, Chief Pharmacist with Kenya Ports Authority  
James Wariero, Pharmacist in Charge of the ART Program at Nyanza Provincial Hospital  
Susan Saddimbah, Pharmacist in Charge of the ART Program at Kenyatta National Hospital  
Amanda Ombeva from MOH/KEMSA





## **Next Steps**

0. RPM Plus will work in collaboration with USAID/OHA, USAID/Kenya, partner cooperating agencies, the local government and local partners, to provide technical assistance to continue to strengthen the pharmaceutical management system and the laboratory services at CPGH, Port Reitz District Hospital, Bomu Medical Centre to support the introduction of ART as agreed in the implementation plans.

RPM Plus will review and revise the draft Pharmacy SOPs for Port Reitz District Hospital and Bomu Medical Centre Pharmacy in November 2004.

RPM Plus will support CPGH to

- Revise and update implementation plans for pharmacy and laboratory services based on the outcome of the meeting held on June 2, 2004
  - Assist CPGH to finalise and approve pharmacy and laboratory SOPs developed for the ART Program
  - Develop and test the manual methodology for quantifying needs of ARVs.
0. In collaboration with FHI/IMPACT and Horizons, RPM Plus will meet with Magongo and municipal council staff to develop implementation plans for strengthening the pharmacy and laboratory services in preparation for ART start up later in 2004
  0. The final report of the RPM Plus assessment will be finalized and disseminated by end of November, 2004.
  0. The report of the NASCOP/RPM Plus site visits will be finalized and shared for comment in November 2004.

## **Adjustments to Planned Activities and/or Additional Activities**

Review of the pharmacy SOPs for Bomu Medical Centre, handover of Quantification Workbooks to CPGH and Bomu Medical Centre and analysis of ADR data were postponed due to absence and conflicting schedules of site staff.